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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
AUDET, MAURY A	
ART UNIT	**PAPER NUMBER**
1654	9

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/973,385	SOLTZ ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *8-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

1 The Information Disclosure Statement filed March 14, 2002 has been considered. An initialed copy of Form PTO-1449 in accordance with MPEP § 609 is attached.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121. In accordance with 37 CFR 1.142, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-7, drawn to a product (tissue adhesive patch), classified in class 514, subclass 2, class 424, subclass 92.

II. Claims 8-11, drawn to a method of making a tissue adhesive patch, classified in class 199, subclass 91.

Invention II and Invention I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product (tissue adhesive patch) can be made by another and materially different process, for instance purification and derivitization of collagen using different chemical steps, processes, or even functional groups (beyond SH- and COO-), followed by incorporation of the peptide and other components into a composition. Therefore, these Inventions are patentably distinct.

The inventions are distinct, each from the other because of the following reasons:

Invention I and II above are independent and distinct, each from the other. They have acquired a separate status in the art (i.e. classification) as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference, which would anticipate the invention of one group, would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Restriction for examination purposes is therefore proper.

During a telephone conversation with Stephen J. Holmes, Attorney for Applicant, on March 13, 2003, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-7. Group II, claims 8-11 were withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Status of the Claims

3 Claims 1-11 are pending. Claims 8-11 are withdrawn from consideration, as nonelected subject matter. Claims 1-7 are examined on the merits.

Objections

4. Claim 1 is objected to because of the following informalities:

The claim needs to be tabbed in, aligned with succeeding claims.

Appropriate correction is required.

Rejections

35 U.S.C. § 112, 2nd ¶

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. In claim 1, it is unclear what is meant by the phrase "mesh structure"? The specification describes three polymers and two wires, and alternatively collagen fibers. However, as described, any mesh structure, i.e. a woven tarp or a chain link fence, could satisfy the limitation of a mesh structure.

b. In claim 3, it is unclear what constitutes the "material". Specification page 7-8 , while indirectly indicating that deionized water, pepsin (removed though in Step. 11), and NaCl may constitute a portion of the material, which the derivatized collagen is concentrated within; the claim language does not even disclose to the public whether deionized water and NaCl are even in the end-product 'material', or if they have been essentially filtered out as well, leaving only concentrated derivatized collagen as the 'material'. As claimed, any material that could include/comprise the derivatized collagen and encapsulated mesh structure, is within the scope of the claims, and it is therefore unclear as to what constitutes 'material'.

c. In claim 3 (and depending claims 5-7), the tissue adhesive patch comprises a "structural component". It is unclear as to what specifically constitutes this "structural component" within the invention? There is no description for a structural "component" found in the specification. As claimed, any "structural component", i.e. a bearing from a mechanical apparatus, could satisfy the limitation "structural component". Specification page 9 narrowly describes a "structural *element* such as fibers [] or mesh". Furthermore, the specification only teaches

"collagen" fibers (p. 16, last ¶), and that the mesh consists of "a polymer (e.g. nylon, polyester, or polycarbonate), [and] carbon or metal wire" (p. 16, 1st ¶). Assuming the structural element is the equivalent of the claimed structural component, Applicant must distinctly claim the 'structural component' of claim 3. Notwithstanding other rejections of claim 3 (112 1st scope; 102/103 prior art), in order to overcome the 112 2nd rejection, Applicant may be able to overcome this rejection by recitation of the "structural element/component, said structural element consisting of collagen fibers and a mesh consisting of a carbon or metal wire and a polymer selected from the group *consisting of* nylon, polyester or polycarbonate".

d. In claim 4, the claim recites "wherein a mesh structure, said mesh structure". It is unclear what Applicant is claiming, as it cannot be determined if claim elements have been omitted after the first recitation of mesh structure, or whether it is a grammatical error and "a mesh structure" is to be removed?

e. In claim 5, the tissue adhesive patch comprises a structural component is "substantially conductive". It is unclear what amount of conductivity constitutes 'substantially'. The specification does not define the conductivity range or measure which the structural component must contain in order to function within the invention. Thus, use of the term "substantially" must be quantified or clarified in some fashion to clarify what Applicant regards as 'substantially' conductive.

f. Additionally in claim 5, it is unclear what is meant by "substantially conductive". As the structural component/element is unclear as claimed, it is also unclear as to what part(s) of the structural component/element are conductive. As discussed in § a., the structural component (assume element) is described in the specification as constituting carbon and metal wire, and

collagen fiber [the 'substantial' conductivity of these three is not described]. Thus, further limiting the structural component/element as conductive is unclear, since what may constitute the former has not been clearly described or claimed.

35 U.S.C. § 112, 1st ¶ Scope of Enablement

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

a. Claims 1, 2 and 4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a mesh structure consisting of collagen fibers and a mesh consisting of a carbon or metal wire and a polymer selected from the group *consisting of* nylon, polyester or polycarbonate, does not reasonably provide enablement for *any and all* mesh structures. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants have reasonably described on specification page 16, 1st ¶, that the tissue adhesive patch consists of a mesh [structure] formed of a polymer, selected from the group consisting of nylon, polyester, and polycarbonate, [and] carbon or metal wire, that is *biologically compatible and non-irritating*. However, the claims encompass any and all mesh structures, whether made of polymers and wires, or not; and whether such mesh structures are biologically compatible and non-irritating, or not. Applicants have not enabled such a broad scope.

Based on the highly unpredictable and complex nature of determining biocompatibility (see Conroy, 1998, ¶ 1, and also at http://64.55.151.178/PDFs/Aqueous_Lubricious_

Coating.pdf; teaching the challenge, in the medical research fields, of determining the biocompatibility of polymers and other materials for use in medical products) from the gamet of materials that could form a mesh structure encompassed by the instant claims, as well as their effective 'conductive' capabilities necessary for function application of the invention, would require undue experimentation without a reasonable expectation of success by one of skill in the art.

b. Claims 1 and 4 are further rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polymers nylon, polyester, and polycarbonate, does not reasonably provide enablement for any and all polymers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants have reasonably described on specification page 16, 1st ¶, that the tissue adhesive patch consists of a mesh [structure] formed of a polymer, selected from the group consisting of nylon, polyester, and polycarbonate, [and] carbon or metal wire, that is *biologically compatible and non-irritating*. However, the claims encompass any and all polymers, whether nylon, polyester, or polycarbonate, or not; and whether such polymers are biologically compatible and non-irritating, or not. Applicants have not enabled such a broad scope.

Like the rejection under mesh structure in a., and based on the highly unpredictable and complex nature of determining biocompatibility (see Conroy, 1998, ¶ 1, and also at http://64.55.151.178/PDFs/Aqueous_Lubricious_Coating.pdf; teaching the challenge, in the medical research fields, of determining the biocompatibility of polymers and other materials for use in medical products), determining which potential polymers from the gamet of polymers that

could be used in a mesh structure encompassed by the instant claims, would require undue experimentation without a reasonable expectation of success by one of skill in the art.

c. Claims 3, and 5-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a structural component (assuming defined as 'element' in specification) consisting of collagen fibers or mesh consisting of a carbon or metal wire and a polymer selected from the group *consisting of* nylon, polyester or polycarbonate, does not reasonably provide enablement for *any and all* "structural components". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants have reasonably described on specification page 16, that the tissue adhesive patch consists of a structural element ('component') formulated of fibers (only collagen, 3rd ¶) or mesh [1st ¶] (only polymers selected from the group consisting of nylon, polyester, and polycarbonate, [and] carbon or metal wire, 1st ¶), assumably that is *biologically compatible and non-irritating* [1st ¶]. However, the claims encompass any and all fibers, whether collagen or not; or any and all mesh structures, whether made of polymers and wires, or not; and whether such fibers or mesh structures are biologically compatible and non-irritating, or not. Applicants have not enabled such a broad scope.

Based on the highly unpredictable and complex nature of determining biocompatibility (see Conroy, 1998, ¶ 1, and also at http://64.55.151.178/PDFs/Aqueous_Lubricious_Coating.pdf; teaching the challenge, in the medical research fields, of determining the biocompatibility of polymers and other materials for use in medical products), determining which potential mesh structures (polymers, wires, and any and all other fibers and mesh-type

structures) from the gamet of materials that could be used as fibers or mesh structures encompassed by the instant claims, as well as their effective 'conductive' capabilities necessary for functional application of the invention, would require undue experimentation without a reasonable expectation of success by one of skill in the art.

d, f. In response to the ~~four~~ 3 112 1st scope of enablement rejections, Applicant is asked to claim in full, clear, concise and exact terms, the elements of the invention as to enable *any* person skilled in the art to make and use the invention as claimed.

35 U.S.C. § 102: Anticipation

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, and 5-6 are rejected under § 102, as anticipated by Wallace et al. (US 6,495,127B).

The claimed invention is drawn to a "a tissue adhesive patch, comprising a mesh structure (carbon or metal wire (cl. 4) including a polymer (including nylon, polyester or polycarbonate (cl. 2)), encapsulated in a material including a derivatized collagen (cl. 1). The claimed invention is also more broadly drawn to a tissue adhesive patch, comprising a structural component (substantially conductive (cl. 5); includes a plurality of fibers (cl. 6) that are coaligned (cl. 7)), embedded in a material including a derivatized collagen.(cl. 3).

Wallace et al. teach Applicants claims 1-3, and 5-6, by describing that a derivatized collagen (column 12, lines 56-57) within a material (column 11, lines 28-29, 44) may be used in dried sheets or as coating (encapsulating/embedding) for "artificial patches or meshes" [i.e. mesh

or structural component] (column 4, lines 10-16 and column 15, line 37-43), wherein a mesh-like core may include a polymer selected from the group consisting of nylon, polyester, or polycarbonate (column 7, line 43-47). Wallace et al. also teach Applicants claims 5-6; wherein a material including derivatized collagen and coating [embedding] artificial patches or meshes [structural component] (column 15, lines 42-43), may also include afibrillar, microfibrillar, and fibrillar collagen [i.e. substantially conductive structural material] (column 10, lines 43-46), and includes collagen fibers [i.e. a plurality of fibers] (column 18, lines 4-8). Wallace et al. does not specifically teach a carbon or metal wire (cl. 4) or coaligned fibers (cl. 7).

35 U.S.C. § 103 Obviousness

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al., in view of Ding (US 6,547,806) and Shastri et al. (US 6,471,993B).

The teachings of Wallace et al. are discussed above.

Ding teaches a photopolymerizable (column 1, ¶ 1) sealing member comprising a fluid-impervious film of polymers selected from at least the group of nylon, polyester, and polycarbonate (column 7, line 50-56) and carbon or metal wire (column 5, lines 23-27), that may be embedded/encapsulated in collagen (column 11, line 49-55). Specifically, Ding teaches:

> . . . the sealing member of this embodiment comprises a plurality of wires . . . [column 5, lines 6-8] the wires can be formed of any suitable resilient material. Various metals, such as stainless steel, or metal alloys can be used. Alternatively, any suitable polymeric

> material could be used (such as carbon *fiber*-reinforced biocompatible resin). [column 5, lines 23-27] The sealing member may be soldered, welded, or glued . . . [f]or example, any suitable eutectic braze can be used. [column 5, lines 43-44]

As noted above, Wallace et al. does not specifically teach a mesh structure with carbon or metal wire; however, Wallace et al. does teach the addition of *Vicryl*, an *implantable mesh* that is a copolymer of glycolic acid and lactic acid (*thus containing carbon*), to the derivatized-collagen tissue adhesive (column 27, lines 27-32). Applicant's specification page 16 describes that "alternatively, a plurality of *fibers [], carbon or metal* can be dispersed throughout [the derivatized collagen layer. Thus Wallace et al.'s Vicryl mesh necessarily teach a conductive material, with carbon, as Applicant incorporated in the present invention as either a carbon or metal wire, or carbon and metal dispersements (non-wire). However, the thicker carbon wire of Shastri et al. would have the capacity for greater conductivity, than the carbon fiber of Wallace et al. One of ordinary skill in the art at the time the invention was made would have found it prima facie obvious to use Ding's carbon or metal wire in Wallace's tissue adhesive patch/sheet, because Ding et al. teach a derivatized collagen with fibrous and conductive properties, as Wallace et al. taught, with the specifically recited alternative of greater conducting properties in the form of carbon and metal wires, as Applicant claims in the present invention.

Shastri et al. teach polymer matrices [i.e. patch] for skin tissue engineering/prosthetic materials (i.e. plastic and reconstructive surgery, and in joint repair and replacement . . . organ [skin] equivalents to replace diseased, defective, or injured organs). Shastri et al.'s formed matrices use polymers such as collagen and nylon and polyester. "Natural polymers that can be used in the invention are . . . collagens, including *derivatized collagens* (e.g., alkylated, hydroxylated, oxidized, or PEG-lated collagens, as well as collagens modified by other

alterations routinely made by those skilled in the art). . ." (emphasis added) [column 13, lines 1-6]. Shastri et al. also specifically teach the use of fiber in a matrices to create a tissue attachment structure, where the fiber matrices of the structure has "voids [] elongated and oriented in the same direction" [column 5, lines 45-51]; *thus leaving a co-aligned fiber matrices.* One of ordinary skill in the art at the time the invention was made would have found it prima facie obvious to use Shastri et al.'s fiber matrices, where the fibers are aligned along micro voids, in the derivatized collagen-based tissue sealant of Wallace et al., because Shastri et al. teach the use of fiber and derivatized collagen to engineer tissue which may be used to replace (i.e. seal) injured skin.

Relevant Prior Art

9 The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kelman et al. (with present Applicant Devore; US 519895, Issued June 15, 1993; cited in Applicant's IDS) and Gagnieu (US 5,412,076, Issued May 2, 1995); Sawyer et al. (US 5,690,675, Issued November 25, 1997). As a backdrop, the prior art search revealed that Kelman et al. and Gagnieu both taught early uses of collagen derivatized by both acylation (COO-) and sulfonyl (SH-) methods, as tissue adhesives. Both derivative methods are thus well known in the art. Sawyer et al., is made of record as further clarification that solid forms of collagen-based tissue adhesives (like that of Wallace et al.), are well known in the art to be administrable/referred to as sheets or 'patches':

> The fusible material may be applied to the wound region as a solid phase or as a non-solid dispersible phase. By "solid phase," it is meant that the fusible material is formed as a *sheet*, layer, film, strip, *patch*, mesh, or the like, over the wound region. By "non-solid dispersible phase," it is meant that the fusible material is in the form of a liquid, gel, powder, or combinations thereof, which may be spread, sprayed, painted, or otherwise dispersed over the wound region. Regardless of its initial state, the fusible material will

be in the form of a solid or gel layer after energy has been applied according to the method of the present invention. That is, solid sheets, layers, films, strips, patches, and the like, will remain as a solid (although the dimensions may alter slightly as the material is softened and fused to the underlying tissue) while meshes and non-solids will be converted into solid or gel layers. [column 2, lines 61-67, and column 3, lines 1-9]

Conclusion

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MA
April 17, 2003

MICHAEL MELLER
PRIMARY EXAMINER